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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/003,405	12/06/2001	Yong-Ling Ruan	021565-110	5391

7590 12/20/2005
R. Danny Huntington, Esq.
BURNS, DOANE, SWECKER & MATHIS, L.L.P.
P.O. Box 1404
Alexandria, VA 22313-1404

EXAMINER

KALLIS, RUSSELL

ART UNIT PAPER NUMBER

1638

DATE MAILED: 12/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/003,405		RUAN ET AL.	
	Examiner		Art Unit	
	Russell Kallis		1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-30 is/are pending in the application.
- 4a) Of the above claim(s) 4-7 and 18-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8-10, 12-17 and 21-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/29;9/16;9/27</u> . | 6) <input checked="" type="checkbox"/> Other: <u>attached sequence report</u> . |

DETAILED ACTION

Claim 11 is canceled. Claims 1-10 and 12-30 are pending. Claims 4-7 and 18-20 are withdrawn. Claims 1-3, 8-10, 12-17 and 20-30 are examined.

Information Disclosure Statement

The IDS submitted 9/18/2005 has not been entered into the record. The submission contains hyperlinks and is therefore objected to. Further, Applicant should identify each entry by GenBank Accession number, briefly identify the source (i.e. plant species), name the encoded enzyme, and provide the date the accession was made publicly available.

Rejection of claims 1-3, 8-17 and 21-30 under 35 U.S.C. 112, first paragraph, is withdrawn in view of Applicant's amendments and arguments.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 8-10, 12-17 and 20-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of altering fiber development or properties, or improving fiber yield or quality, or for increasing seed size in a cotton plant transformed with a plant sucrose synthase and plants and seeds transformed thereby, does not reasonably provide enablement for altering the fiber properties or development, or improving fiber yield or quality, or for increasing seed size of any plant other than cotton. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are broadly drawn to a method for altering fiber development or properties, a method of improving fiber yield, a method of improving fiber quality, and a method of increasing seed size by providing cells of a plant with a polynucleotide capable of being translated into an active sucrose synthase, and plants and seeds transformed thereby.

Applicants provide guidance for reducing fiber and seed development in cotton transformed with antisense and co-suppression constructs comprising an undefined polynucleotide encoding an unspecified sucrose synthase (Example 1 page 25).

The specification fails to provide guidance for using the other polynucleotides encompassed by the claims that encode an active sucrose synthase that would alter fiber development, improve fiber yield, improve fiber quality, or increase seed size by providing cells of plants with a polynucleotide capable of being translated into an active sucrose synthase. Applicants fail to teach which sucrose synthase encoding polynucleotides would alter fiber development other than SEQ ID NO: 1. Further, Applicant does not teach any increases or

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improvements in fiber quality, or size; or any increases in seed size using any of the sucrose synthases taught in the specification.

The state of the art for transformation of a plant with a sucrose synthase encoding polynucleotide in order to increase or alter fiber development is unpredictable because in many plants sucrose synthase enzymatic activity does not largely impact fiber development or properties. Three isoforms of pea sucrose synthase were cloned and characterized. It was observed in mutants of the pea sucrose synthase that some isoforms were active in the production of starch and others were active in the production of cellulose (Barratt D. et al. Plant Physiology, October 2001 Vol. 127; pp. 655-664; see abstract and page 658, column 2, beginning of new section). Further, different isoforms of sucrose synthase serving separate physiological roles is also seen in other plant species. For example, the corn SS1 isoform of sucrose synthase plays the dominant role in providing carbon for cellulose biosynthesis while SS2 serves to provide carbon precursors for starch biosynthesis (Chourey P. et al. Mol. Gen. Genet. 1998, Vol. 259, pp. 88-96; see abstract and page 89 column 1, last paragraph of the introduction). The above mutants in corn and in pea did not show any altered fiber development or properties but rather are related to starch synthesis (Ruan Y. et al. Plant Physiology, Vol. 115, pp. 375-385; see page 375, column 2 lines 4-17). Since all plants produce fiber, the above mutants in corn or pea indicate that that not all plants would yield altered fiber development or properties or improvements to fiber quality or increased seed size when transformed with a sucrose synthase. Moreover the specification does not support a broad range of plants defined as fiber producing plants other than cotton.

Given the lack of guidance in the instant specification, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified fiber producing plants as broadly claimed to encompass any plant by *in vivo* transformation and analysis of fiber properties or development and seed size, in order to identify those plants that when transformed would produce an altered fiber development or properties, or improved fiber yield, improved fiber quality, or increased seed size by providing any plant with a sucrose synthase as broadly claimed.

Therefore, given the breadth of the claims; the lack of guidance and working examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled for the full scope of the claims.

Applicant asserts that in view of the declaration of Dr. Arioli the invention is enabled over the full range of plants. The declaration of Dr. Arioli is directed to establishing that the methods taught in the specification enabled the transformation of cotton to overexpress SuSy as set forth in Example 3 of the specification. Although the various isoforms of SuSy appear to work interchangeably, it also appears that there is a requirement for a sufficient physiological context for fiber production in a plant and that the specification provides guidance with respect to cotton and only cotton in this respect (Also see arguments *supra*).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 22-23 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed inventions encompass untransformed seeds, which are a product of nature and not one of the five classes of patentable subject matter. Claims 22-23 and are drawn to parts such as seeds of the transformed plant. Due to Mendelian inheritance of genes, a single gene introduced into a parent plant would only be transferred at most to half the male gametes and half the female gametes. This translates into only two thirds of the seeds having at least a single copy of the transgene and one quarter of the seeds would not carry a copy of the transgene. Since the claim encompasses seeds that lack the transgene, the claim encompasses seeds that are indistinguishable from seeds that would occur in nature. See *American Wood v. Fiber Distintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brogdex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 8-10, 12-17 and 20-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conner U.S. Patent 6,080,914 (published 27 June 2000) in view of Ruan Y. *et al.* Plant Physiology, Vol. 115, pp. 375-385 and in further view of Applicant's specification.

The claims are broadly drawn to a method for altering fiber development or properties, a method of improving fiber yield, a method of improving fiber quality, and a method of increasing seed size by providing cells of a plant with a polynucleotide capable of being translated into an active sucrose synthase, and plants and seeds transformed thereby.

Conner teaches transforming cotton seeds and bolls with a sucrose synthase for enhanced sink activity (column 10 lines 1-15 and Claims 6 and 9)

Ruan teaches that SuSy expression controls cellulose biosynthesis in plant cells (page 376 column 1, lines 9-24; and the Abstract and page 383, column 1 first full paragraph to page 384 to the end of the section).

Applicant's specification teaches that a cotton clone encoding SEQ ID NO: 2 (Accession U74588 made public on May 4, 1999; see page 1 of specification and attached sequence report), the constitutive clover stunt virus promoter (page 6 of the specification) and a method of cotton transformation was known in the art (page 25 of the specification).

It would have been obvious at the time of invention to modify the invention of Conner to transform cotton with a construct that directed expression in the ball or seed of a cotton plant. One of skill in the art would have been motivated by the teachings of Conner that cotton ball and seed were useful in the art for transformation in order to modify and increase the storage material therein (i.e. cellulose fibers) and by the knowledge that the genes encoding the enzymes required for fiber production in fiber producing cells of cotton were available and commonly known in

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the art as taught by Raun, and Applicant's specification; and that cotton fiber producing seed cells contain the necessary physiological context for altering fiber production also taught by Ruan, and by the success of cotton transformation techniques and producing endosperm cells of rice seeds that accumulated phytoene; that one of ordinary skill would recognize the above teachings and would have had a reasonable expectation of success in transforming a cotton cotton plant with a SuSy coding sequence that would result in the production of altered fiber or seed size given that diverse patterns of carbon portioning in the developing cotton seed as taught by Ruan; and wherein incorporation of a constitutive clover stunt virus promoter or the cotton SuSy clone encoding the SuSy enzyme of SEQ ID NO: 2 is obvious given the lack of criticality.

All claims are rejected.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Russell Kallis Ph.D.
December 7, 2005

RUSSELL P. KALLIS, PH.D.
PATENT EXAMINER

A handwritten signature in cursive script that reads "Russell Kallis".

GenCore version 5.1.6
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OM nucleic - nucleic search, using sw model

Run on: June 4, 2004, 21:00:05 ; Search time 16233 seconds

(without alignments)
7008.899 Million cell updates/sec

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13: gb_un:*

14: gb_vl:*

15: gb_wa:*

16: em_fun:*

17: em_hum:*

18: em_in:*

19: em_mu:*

20: em_om:*

21: em_or:*

22: em_ov:*

23: em_pat:*

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25: em_pl:*

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28: em_un:*

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41: em_hcg_other:*

Attached sequence report

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and is derived by analysis of the total score distribution.

SUMMARIES

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4	1602.6	61.1	2682	AF030231	AF030231 Glycine m
5	1577.2	60.1	2738	AF315375	AF315375 Phaseolus
6	1559	59.4	2728	MT131943	AJ131943 Medicago
7	1556	59.3	2652	PSA012080	AJ012080 Pisum sat
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ALIGNMENTS

RESULT 1

U73588 2625 bp mRNA linear PLN 04-MAY-1999

LOCUS U73588

DEFINITION Gossypium hirsutum sucrose synthase mRNA, complete cds.

ACCESSION U73588

VERSION U73588.2 GI:4733945

KEYWORDS

SOURCE Gossypium hirsutum (upland cotton)

ORGANISM Gossypium hirsutum

REFERENCE

1 (bases 1 to 2625)

Perez-Grau, L. and Delmer, D.

TITLE

Direct Submission

Pred. No. is the number of results predicted by chance to have a

JOURNAL Submitted (07-OCT-1996) Calgene, Inc., 1920 Fifth Street, Davis, CA

9616, USA On May 4, 1999, this sequence version replaced gi:4098126.

COMMENT Location/Qualifiers

FEATURES

Source

CDS

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ORIGIN polyA_site

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RESULT 2
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 AB022092
 ACCESSION

VERSION
 AB022092.1 GI:6682842
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 ORGANISM
 Citrus unshiu
 REFERENCES
 1 Komatsu, A., Moriyasu, T., Koyama, K., Omura, M. and Akhama, T.
 Analysis of sucrose synthase genes in citrus suggests different
 roles and phylogenetic relationships
 J. Exp. Bot. 53 (366), 61-71 (2002)
 MEDLINE
 11741042
 JOURNAL
 2 (bases 1 to 2661)
 REFERENCE
 Komatsu, A.
 Direct Submission
 Submitted (22-DEC-1998) Akira Komatsu, National Institute of Crop
 Science, 2-1-18, Tsukuba Science City, Ibaraki 305-8518, Japan
 (E-mail: akomatsu@affrc.go.jp, Tel: 81-298-38-8949,
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polya_site

ORIGIN

Query Match 64.4%; Score 1669.6; DB 8; Length 2661;
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